K072619 #1/4

Summary of Safety and Effectiveness

Submitter:	Zimmer, Inc. P.O. Box 708 Warsaw, IN 46581-0708
Contact Person:	Daniel J. Williman Specialist, Corporate Regulatory Affairs Telephone: 574-371-8065 Fax: (574) 372-4605
Date:	September 14, 2007
Trade Name:	*NexGen*® Complete Knee Solution LPS-Flex Porous Femoral Component, *NexGen* Knee *Gender Solutions*™ Female (GSF) Porous Femoral Components
Common Name:	Total Knee Prosthesis
Classification Name and Reference:	Knee joint, patellofemorotibial, metal/polymer, porous-coated, uncemented prosthesis -- 21 CFR § 888.3565 Knee joint, patellofemorotibial, polymer/metal/polymer, semi-constrained, cemented prosthesis -- 21 CFR § 888.3560
Predicate Devices:	*NexGen* Complete Knee Solution Porous, Uncemented Femoral and Tibial Baseplate Components, manufactured by Zimmer, Inc. (K031061, cleared October 9, 2003) *NexGen* Knee *Gender Solutions* Female (GSF) Femoral Components, manufactured by Zimmer, Inc (K060370, cleared April 28, 2006)
Device Description:	The LPS-Flex Fixed-bearing Knee is a semi-constrained, condylar system for use without the cruciate ligaments when additional stability is required to prevent anterior subluxation of the femur relative to the tibia in flexion. The LPS-Flex

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Porous femoral component is designed to have a maximum active, load bearing range of motion of 155 degrees. It contains a fiber metal pad to allow for cementless use.

The GSF Porous femoral components include both LPS-Flex GSF and CR-Flex GSF versions and are part of the Zimmer Flex-series of semi-constrained, non-linked, condylar knee prostheses that are designed to have a maximum active, load bearing range of motion of 155 degrees. The GSF designation indicates that the femoral component is designed to better match distal femoral anatomic features more typical of female patients. They contain fiber metal pads to allow for cementless use.

Intended Use:

General Indications for the *NexGen* Complete Knee Solution Femoral Components:

- This device is indicated for patients with severe knee pain and disability due to:
  - Rheumatoid arthritis, osteoarthritis, traumatic arthritis, polyarthritis.
  - Collagen disorders, and/or avascular necrosis of the femoral condyle.
  - Post-traumatic loss of joint configuration, particularly when there is patellofemoral erosion, dysfunction or prior patellectomy
  - Moderate valgus, varus, or flexion deformities.
  - The salvage of previously failed surgical attempts or for a knee in which satisfactory stability in flexion cannot be obtained at the time of surgery.

Porous coated femoral components may be used cemented or uncemented (biological fixation).

Specific Indications for the LPS-Flex Porous Femoral Components:

- LPS- Flex porous coated femoral and tibial baseplate components may be used cemented or uncemented (biological fixation).
- Specific uses with the LPS-Flex femorals:

- Provides increased flexion capability for patients who have both the flexibility and desire to increase their flexion range.
- The LPS-Flex femoral, when used with the LPS-Flex articular surfaces, is designed for use with both cruciate ligaments excised and when load bearing range of motion (ROM) is expected to be less than or equal to 155 degrees.

Specific Indications for the *NexGen* Knee GSF Knee Porous Femoral Components:

- CR-Flex GSF and LPS-Flex GSF porous coated femoral components may be used cemented or uncemented (biological fixation).
- Specific uses with CR-Flex GSF or LPS-Flex GSF femorals:
  - Provides increased flexion capability for patients who have both the flexibility and desire to increase their flexion range.
  - The CR-Flex GSF femoral, when used with 90-prefix *NexGen* CR articular surfaces, 00-prefix 10, 12 or 14mm or 90-prefix 17 or 20mm *Prolong*™ Highly Crosslinked Polyethylene CR articular surfaces, or with *Gender Solutions Natural-Knee*® Flex Congruent articular surfaces, is designed for use with a functional posterior cruciate ligament and when load bearing range of motion (ROM) is expected to be less than or equal to 155 degrees.
  - The LPS-Flex GSF femoral, when used with LPS-Flex articular surfaces, is designed for use with both cruciate ligaments excised and when load bearing ROM is expected to be less than or equal to 155 degrees.

Comparison to Predicate Device:

The LPS-Flex Porous femoral component geometry differs slightly from that of the predicate LPS Porous femoral component. However, the articulating geometry is identical to that of the LPS-Flex femoral component substrate.

The LPS-Flex Porous GSF and CR-Flex Porous GSF femoral component geometries are identical to those of their predicate devices, the LPS-Flex GSF and CR-Flex GSF.

Except for slight differences in shape, the fiber metal pads on all of the proposed femoral components are identical to the fiber metal pads of the porous-coated predicate devices.

Performance Data (Nonclinical and/or Clinical):

Non-Clinical Performance and Conclusions:

Mechanical testing of the proposed devices indicate that they are substantially equivalent to the predicate devices.

Clinical Performance and Conclusions:

Clinical data and conclusions were not needed for these devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Zimmer, Inc.
% Mr. Daniel J. Williman
Specialist, Corporate Regulatory Affairs
P.O. Box 708
Warsaw, Indiana 46581-0708

Re: K072619
Trade/Device Name: NexGen® Complete Knee Solution LPS-Flex Porous Femoral Component, NexGen Knee Gender Solutions™ Female (GSF) Porous Femoral Components
Regulation Number: 21 CFR 888.3565
Regulation Name: Knee joint, patellofemorotibial metal/polymer porous-coated uncemented prosthesis
Regulatory Class: Class II
Product Code: MBH, JWH
Dated: September 17, 2007
Received: September 19, 2007

Dear Mr. Williman:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K072619

Device Name:

NexGen® Complete Knee Solution LPS-Flex Porous Femoral Component, *NexGen* Knee *Gender Solutions*™ Female (GSF) Porous Femoral Components

Indications for Use:

General Indications for the *NexGen* Complete Knee Solution Femoral Components:

- This device is indicated for patients with severe knee pain and disability due to:
  - Rheumatoid arthritis, osteoarthritis, traumatic arthritis, polyarthritis.
  - Collagen disorders, and/or avascular necrosis of the femoral condyle.
  - Post-traumatic loss of joint configuration, particularly when there is patellofemoral erosion, dysfunction or prior patellectomy
  - Moderate valgus, varus, or flexion deformities.
  - The salvage of previously failed surgical attempts or for a knee in which satisfactory stability in flexion cannot be obtained at the time of surgery.

Porous coated femoral components may be used cemented or uncemented (biological fixation).

Specific Indications for the LPS-Flex Porous Femoral Components:

- LPS- Flex porous coated femoral and tibial baseplate components may be used cemented or uncemented (biological fixation).
- Specific uses with the LPS-Flex femorals:
  - Provides increased flexion capability for patients who have both the flexibility and desire to increase their flexion range.
  - The LPS-Flex femoral, when used with the LPS-Flex articular surfaces, is designed for use with both cruciate ligaments excised and when load bearing range of motion (ROM) is expected to be less than or equal to 155 degrees.

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K072619

Specific Indications for the *NexGen* Knee GSF Knee Porous Femoral Components:

- CR-Flex GSF and LPS-Flex GSF porous coated femoral components may be used cemented or uncemented (biological fixation).
- Specific uses with CR-Flex GSF or LPS-Flex GSF femorals:
  - Provides increased flexion capability for patients who have both the flexibility and desire to increase their flexion range.
  - The CR-Flex GSF femoral, when used with 90-prefix *NexGen* CR articular surfaces, 00-prefix 10, 12 or 14mm or 90-prefix 17 or 20mm *Prolong*™ Highly Crosslinked Polyethylene CR articular surfaces, or with *Gender Solutions Natural-Knee*® Flex Congruent articular surfaces, is designed for use with a functional posterior cruciate ligament and when load bearing range of motion (ROM) is expected to be less than or equal to 155 degrees.
  - The LPS-Flex GSF femoral, when used with LPS-Flex articular surfaces, is designed for use with both cruciate ligaments excised and when load bearing ROM is expected to be less than or equal to 155 degrees.

Prescription Use _X_ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ____ (21 CFR 807 Subpart C)

(Please do not write below this line – Continue on another page if needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Barbara Murray

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K052669